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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,108	10/19/2000	Louise Elizabeth Donnelly	7500-0010	7685

23980 7590 05/21/2004

REED & EBERLE LLP
800 MENLO AVENUE, SUITE 210
MENLO PARK, CA 94025

EXAMINER	
DELACROIX MUIRHEI, CYBILLE	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/694,108	DONNELLY ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,24-28,30-33,35,36,38 and 40-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-14,24-28 and 38* is/are allowed.

6)☒ Claim(s) *30-33,35,36 and 40-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The following is responsive to Applicant's amendment received Jan. 21, 2004.

Claims 15-23, 29, 34, 37, 39 are cancelled. New claims 41-44 are added. Claims 1-14, 24-28, 30-33, 35-36, 38, 40-44 are currently pending.

The previous claim objection set forth in paragraph 1 of the office action mailed Oct. 17, 2003 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejections under 35 USC 112, second paragraph, set forth in paragraphs 2-4 of the office action mailed Oct. 17, 2003 **are withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous rejection of claims 29, 31-33, 39, 40 under 35 USC 103(a) set forth in paragraphs 5-6 of the office action mailed Oct. 17, 2003 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous rejection of claims 30, 35, 36 under 35 USC 103(a) set forth in paragraphs 7-8 of the office action mailed Oct. 17, 2003 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's amendment has necessitated the following new ground(s) of rejection.

New Ground(s) of Rejection

Claim Objection(s)

1. Claim 42 is objected to because of the following informalities: in claim 42, line 2, the term "and" should be deleted and replaced with –or--. Appropriate correction is required.

Claim Rejection(s)—35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 recites the limitation "the long acting beta-adrenergic agonist..." in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 31, 33, 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over FISCHER et al., 6,329,422 (already of record) in view of CAZZOLA et al. (submitted by Applicant) and WO 94/04148 ('148) and NOTARIO et al., 6,551,616 and BARBIER, 4,176,180.

FISCHER et al. disclose pharmaceutical compositions for treating cystic fibrosis, chronic bronchitis or asthma, the compositions comprise active agents such as resveratrol and pharmaceutically acceptable aerosol propellants useful for endopulmonary and/or intranasal inhalation administration. The compositions may also be administered orally. Please see col. 6, lines 58-67; col. 11, lines 47-60; col. 12, lines 61-63; col. 13, lines 24-30; claim 28.

FISCHER et al. do not disclose administering a composition containing resveratrol in combination with a macrolide antibiotic such as erythromycin or clarithromycin. However, the Examiner refers to (1) CAZZOLA, which discloses that erythromycin or

clarithromycin may prove useful in treating asthma (please see page 234, second column, first and second full paragraph); (2) WO 148, which discloses the use of macrolide antibiotics for treating asthma, wherein the antibiotics may be administered orally or by inhalation (please se pages 2-3 and 5-6); (3) NOTARIO, which discloses administration of clarithromycin to patients suffering from chronic bronchitis (please see col. 11, lines 27-33); and (4) BARBIER, which teaches administration of a composition containing erythromycin to a patient suffering from chronic bronchitis (please see col. 6, lines 34-39).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the compositions of FISCHER to additionally include macrolide antibiotics such as erythromycin or clarithromycin because such a modification would have been motivated by the reasonable expectation that the combined effect of resveratrol and macrolide antibiotic would successfully treat patient suffering from asthma or chronic bronchitis. Furthermore, one of ordinary skill in the art would reasonably expect the antibiotics to treat or prevent any infections that may result from or accompany the asthma or bronchitis.

With respect to claim 40 drawn to the use of the composition for treating ILD, If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51

USPQ2d 1161, 1165 (Fed. Cir. 1999). See also Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"). As far as the instant application is concerned, the body of the pharmaceutical composition claim defines a structurally complete invention while merely providing in the preamble a statement of intended use. Therefore, that preamble is not a claim limitation.

4. Claims 30, 32, 35, 36 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. in view of CAZZOLA et al. and WO 94/04148 ('148) and NOTARIO et al. and BARBIER, supra as applied to claims 31, 33, 40-43 above, and further in view of American Drug Index (already of record) and Goodman & Gilman's (already of record).

Fischer, Cazzola, WO '148, Notario and Barbier as applied above.

However, these references do not disclose that the compositions may also include a long acting β-adrenergic agonist such as salmeterol xinafoate; however, the Examiner turns to (1) the American Drug Index, which discloses that salmeterol xinafoate is a known bronchodilator and (2) Goodman & Gilman's which teaches that β-adrenergic agonists are known anti-asthmatics (Goodman & Gilman's, pages, 664-665).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the compositions of FISCHER, Cazzola, WO' 148, Notario and Barbier to include a bronchodilators/anti-asthmatic such as salmeterol xinafoate/β-adrenergic agonist, as taught by American Drug Index and Goodman &

Gilman's, because one of ordinary skill in the art would reasonably expect these bronchodilators/anti-asthmatics to aid in the treatment of a patient suffering from asthma. In other words, one of ordinary skill in the art would reasonably expect that the combination of resveratrol, macrolide antibiotics and bronchodilators/anti-asthmatics would successfully and comprehensively treat a subject suffering from asthma or chronic bronchitis.

Concerning the claims drawn to the use of a dry powder, the use of a dry powder in inhalation compositions is obvious in view of WO '148 which disclose compositions for administration through inhalation where the compositions comprise a dry powder, wherein the particle size is in the range of 0.01 to 10μm. Please refer again to WO '148, page 6, lines 10-30.

In addressing claim 35, the use of a pharmaceutical sugar as a carrier is obvious and well within the capability of the skilled artisan.

Conclusion

Claims 30-33, 35-36, 40-44 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 571-272-0572. The examiner can normally be reached on Mon-Fri from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached at 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

May 16, 2004

MARIANNE C. SEIDEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600